Attachment B - Recommendation for Recall Classification

Update and transmit the electronic record in RES with the required information necessary for the CRU to review and classify the recall. RES will, via Outlook Email, automatically notify the appropriate center and OEIO/DE personnel of the recommendation through established Outlook lists. Guidance for information to be included in the recommendation is as follows:

1. Product Description (INT), Trade Name, and Product Usage fields- (Product Details and Center Specific Pages)

a. For each product, provide as applicable: Pertinent labeling to identify the product to include the product name (brand and generic) and the intended use or indications. Model and/or catalog numbers which further define the exact product. Describe how it is packaged such as box, flexible plastic, glass bottle or vial; the type such as tablet, sugar coated, or liquid, capsule, or powder; strength; sizes; form; route of administration; shipping or unit package. Provide a brief description of the product and its use. If product labeling does not indicate how the product is to be used, and the health hazard is dependent on use, consult the firm's catalog, the Red Book, or similar sources for the information.

If a drug product, indicate Rx or OTC and include the NDA/ANDA and NDC or UPC codes. For medical devices, obtain and include the 510(k), IDE, or PMA numbers as well as any related Corrections and Removals numbers.

If it is determined that the product must be examined physically for health hazard evaluation and/or to determine the efficacy of the corrective action, collect and ship an appropriate sample to the designated unit via the most expeditious and practical means available. Notify the center of the time, how sent, and estimated time of arrival.

b. For each product give: brand name; name, address, and type of responsible firm on label; number and description of private labels. Submit a complete copy of all labeling (including product inserts or information sheets) to the appropriate CRU by an expeditious method, such as Facsimile, Federal Express, or Overnight Mail, depending on the circumstances involved.

2. Code Information (RES Product Details page)

Code Information (INT) field - List all lot and/or serial numbers, product numbers, packer or manufacturer numbers, sell or use by dates, etc., which appear on the product or its labeling.

3. Recalling Firm/Manufacturer/Responsible Firm (for the violation) – (RES Firm/Contact Details pages)

Recalling Firm Information fields:

FEI field- provide FEI number and click search. If the firm is in the Official Establishment Inventory (OEI) the firm name and address is provided. Complete any fields not automatically populated. If FEI is unknown, or does not exist, type in

"unknown" in the FEI field and then fill in all following information fields. Under the "Comment" box, identify the type of firm, i.e., manufacturer, importer, broker, repacker, own label distributor.

Manufacturer Information field – Same as FEI field! In the "Comment" box, add any information to clarify relationships with either the recalling or responsible firm.

Responsible Firm Information field – Same as FEI field! In the "Comment" box explain the firm's relation to the product such as processor, contract sterilizer, distributor, component supplier, etc.

4. Reason for Recall Recommendation (RES Event Details pages)

Complete Reason for Recall field - provide detailed information as to how the product is defective and violates the FD&C Act or related statutes. Refer to the IOM Chapter 8, Subchapter 810 for inspectional guidance.

a. Include any analytical findings in qualitative and/or quantitative terms, indicating whether firm, FDA, State, or private firm analysis. Indicate the analyzing laboratory. Explain all State involvement in the recall, including sample collection or analysis, recall agreement or initiation, recall monitoring, and product disposition.
b. Provide inspectional (GMP) or other evidence where appropriate.
c. In cases where a veterinary drug product is being recalled due to subpotency of active ingredients prior to labeled expiration date, provide the following information:
   1. The firm's stability testing plan (including analytical methodology) which established the labeled expiration date.
   2. Specific batch numbers in the stability studies and assay values that are the basis of the firm's recall.
   3. Potency specifications which the firm uses for recall purposes.
   4. Final assay values for the active ingredients which were the basis of the initial release of the batch.

   It should be noted whether or not information regarding stability data on file with the firm and the Quality Control procedures used by the firm to determine the potency of the active ingredients, is available in the EIR.

Root Cause field - provide any information available which identifies circumstances which resulted in, or contributed to, the problem which resulted in the recall.

Type of Injury Field – List in chronological order any complaints, injuries, or associated problems with the recalled product(s). Note: specific reference to MDRs and Corrections and Removals Reports are reported elsewhere.

5. Volume of Product in Commerce (RES Event Details page)

Quantity Manufactured field – This calls for the total "event" quantity for the product or products recalled.

Quantity Distributed field (Internet) – This is the total of all products distributed and should be the sum of quantities distributed for all product(s). Note: Each product has its own field for quantity of product distributed.

Manufactured From field – Provides dates.

Expected Life - This could include products such as pacemakers, which have a calculable life span.

Shelf Life - This primarily references perishable foods but may also be used for medical devices, biologics, and certain drugs.

NOTE: If the recommendation is for a FDA Requested Recall, assure that there is, in fact, product remaining in commerce before preparing and submitting the recommendation.

6. Distribution Pattern (RES Event Details page)

Distribution Pattern field (Internet) – This field is to provide the public with the general area of distribution such as, "Distributors in 6 states: NY, VA, TX, GA, FL and MA; the Virgin Islands; Canada and Japan". The term "nationwide" is defined to mean the fifty states or a significant portion of them scattered across the United States. The six United States territories, Guam, Puerto Rico, American Samoa, Virgin Islands, and the Canal Zone, are to be reported separately.

Consignee Details fields

List of Consignees or Comments – This field should be used to list U.S. government, military and/or civilian units/agencies to which product(s) has been distributed. This would include the Defense Personnel Support Center (DPSC), DOD Hospitals, Department of Veterans Affairs (DVA), USDA (especially any product which may reach the school lunch program), or other government agency sales/distribution. If the consignee list is long, it may be submitted separately through the district R&E Coordinator to OEIO/DE. Indicate whether these were direct or contract sales. If there have been contract sales, report the contract number, contract date, and implementation date. Any discussion of product sales, products expected to remain on the market at time of recall, or related topics may be included in comments. (This information is not published on the Internet)

Number of Domestic Consignees – Provide number

Number of Foreign Consignees – Provide Number

Chart - As best you can, check off the types and approximate number of consignees in the chart.

7. Firm's Recall Strategy (RES Event Details page)

Recall Strategy field - If the firm was advised of FDA findings and the problem was discussed with them, report its reactions and recall plans in detail**.** Similarly, if the firm advised FDA of the problem, report and explain the firm's own analytical results and/or information that resulted in the firm's decision to conduct a recall. Obtain the date that the firm realized the need for recall. (Firm Awareness Date on Start Recall page). Describe the firm's planned recall strategy, comment on its adequacy from the district's viewpoint, and evaluate the firm's ability to complete an effective recall. Sections 7.42 and 7.46 of 21 CFR, Part 7 - Enforcement Policy, Subpart C, provide information to be obtained from the firm for CRU evaluation. The firm's strategy should address the depth of the recall, the consideration of a public warning, and an appropriate effectiveness check program. It should also include the firm's intended course of action when an account which distributed the recalled product is found out of business. Include date

recall was initiated, if already underway. If product is to be removed from the market place and recovered, its final disposition should be identified. Provide details of any publicity issued or to be issued by FDA, the firm, the state, or local government.

8. Firm Officials/FDA Contact/Public Contacts (RES Firm/Contact Details page)

Most Responsible Individual field - Provide name, address, and phone number (if available) for the most responsible corporate individual for the recalling firm. If someone other than the most responsible corporate official, or the FDA contact person, are to receive the original or copy of recall classification or termination letters, provide the name(s) under the "Comment" box.

Recall Contact field – list the name, address, phone number, email address, fax number, etc. of the person that is the FDA contact for recall operations.

Public Contact field – list for the recalling firm, either a person or staff such as "Public Relations Staff" that can handle contacts from the public. Include name, address, phone number, facsimile, and email address as applicable.

9. District Audit Program (RES Event Details page)

Effectiveness Check Level field – Provide the firm's planned or district recommended effectiveness level.

Audit Check Level field – Provide the district's recommended audit check level, i.e. the level that the district believes will satisfactorily verify the recall's effectiveness.

Audit/Effectiveness Check Modification box - This box should be used to provide any modifications to the recommended levels, e.g. "Recommend level C (10%) audit checks at distributor accounts and level D (2%) not to exceed five sub accounts of each distributor audited." Provide the firm's recall effectiveness history when recommending low levels of, or no audit checks, and monitoring of recall status from the firm's own records. This box may also be used to provide the district's proposed program for monitoring the recall, including the time table for follow-up visits or firm contacts for reviewing the recall status. State what actions have already been taken by FDA such as inspections, sample collections, etc.